

SEP 27 2005

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## 510(k) Summary

**510(k) Number:**

**Company:** Arthrex, Inc.  
**Address:** 1370 Creekside Blvd., Naples, FL 34108-1945  
**Telephone:** (239) 643-5553  
**Facsimile:** (239) 598-5508  
**Contact:** Ann Waterhouse

**Trade Name:** Arthrex Tenodesis Screw Family  
**Common Name:** Suture Anchor  
**Classification:** Fastener, Fixation  
**Product Code:** HWC, MAI, MBI

**Description:**

The Arthrex Tenodesis Family of screws are manufactured using a variety of polymers or titanium metal. They are threaded, fully cannulated anchors with a rounded head. The Tenodesis Screws are available with specific instrumentation to aide implantation.

**Indications for Use:**

The Arthrex Tenodesis Family of screws, made of various metals and polymers which are intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, foot/ankle, knee, and hand/wrist. Specifically;

*Shoulder:* Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

*Foot/Ankle:* Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

*Knee:* Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

*Elbow:* Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

*Hand/Wrist:* Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/ wrist

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The difference between the Arthrex Bio-Tenodesis Screw, Arthrex Titanium Tenodesis Screws and the predicate devices with similar indications do not raise any questions regarding the safety and effectiveness of the implant. Furthermore, the materials are well characterized and have been used in predicate devices with similar indications. The devices, as designed, are as safe and effective as predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 27 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Ann Waterhouse, RAC  
Regulatory Affairs Project Manager  
Arthrex, Incorporated  
1370 Creekside Boulevard  
Naples, Florida 34108

Re: K051726

Trade/Device Name: Arthrex Tenodesis Family  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC, MAI, MBI  
Dated: September 15, 2005  
Received: September 19, 2005

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Ms. Ann Waterhouse, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K051726

Device Name: Arthrex Tenodesis Family

**Indications for Use:**

The Arthrex Tenodesis Screws are constructed of various polymers and metals and intended to provide soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. Specifically;

*Shoulder:* Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

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*Elbow:* Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

*Hand/Wrist:* Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/ wrist

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use yes  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No  
(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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